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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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07/01/2003

TRANSNATIONAL ENTERPRISES INC
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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/515,806

Applicant(s)

COOK ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-12, 22, 31-33 and 35-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-4, 7-12, 22, 31-33, 35-39 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 1-4, 7-12, 22, 31-33, 35-39 are pending.

Amendment of claims 1, 4, 7-9, 22, 32-33, 35-39, cancellation of claims 5-6, 20-21, 27, 29-30 and 34, in Paper No. 24, filed on 5/27/2003 is acknowledged.

Upon further consideration, the finality of the previous Office Action Paper No. 22, mailed on 3/25/2003 is hereby withdrawn due to new ground(s) of rejection not previously introduced. Specifically, the 35 USC 102(e) rejections set forth below.

As a result of a telephonic interview with David Paglierani on 6/10/2003, Applicant's representative submitted a proposed amendment to claim 4. This amendment however has not been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claim 12 is objected to because of the recitation of "culture medium to, thereby, produce the polypeptide. For clarity, it is suggested that the claim be amended to recite "culture medium to produce the polypeptide. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 22 is indefinite in the rejection of "a kit comprising the nucleic acid molecule of any one of claims 1, 2, 3, or 4 which selectively hybridizes in 0.5 M sodium phosphate, 7% SDS at 65 C, followed by one or more washes....., to a nucleic acid molecule and instructions for use" for the following reasons. As written, the recited hybridization conditions are redundant since the kit already comprises the nucleic acid molecules of any one of claims 1,2, 3, or 4. It is suggested that the claim be amended to recite "a kit comprising the nucleic acid molecule of any one of claims 1, 2, 3, or 4 and instructions for use. For examination purposes, the suggested language will be used. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4, 7-12, 22, 31, 35-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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7. This rejection, which has been discussed at length in Paper No. 18 mailed on 7/12/2002 was previously applied to claims 5-12, 22, 31 and is now applied to claims 4, 7-12, 22, 31, 35-39 for the reasons of record.
8. Applicants argue that the claims as amended render the rejection to these claims moot.
9. Applicant's arguments have been fully considered. While the amendments submitted by Applicants are deemed sufficient to overcome some of the rejections previously applied, the claims as amended contain subject matter which is not adequately described for the following reasons. Claims 4, 7-10, 22, 35-39 are directed to a genus of structural homologs of the polynucleotide of SEQ ID NO: 1 of any function encoding a naturally-occurring variant of a polypeptide having kinase activity. Claims 11-12 are directed to a host cell comprising said genus of polynucleotides and a method of producing the polypeptides encoded by the genus of polynucleotides. While the claim recites the function of the polypeptide from which the variant is derived, there is no recitation of the function of the variant encoded by the claimed polynucleotides. As written, many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification only discloses a single species of the claimed genera which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the claimed genera. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.
10. It is noted that the proposed amendment of claim 4 submitted by Applicants on 6/10/2003 appears to overcome the instant rejection.

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11. Claims 4, 7-12, 22, 31, 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, does not reasonably provide enablement for a structural homolog of the polynucleotide of SEQ ID NO: 1 wherein said homolog encodes a polypeptide of any function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

12. This rejection, which has been discussed at length in Paper No. 18 mailed on 7/12/2002 was previously applied to claims 5-12, 22, 31 and is now applied to claims 4, 7-12, 22, 31, 35-39 for the reasons of record.

13. Applicants argue that the claims as amended, render the rejection to these claims moot.

14. Applicant's arguments have been fully considered. While the amendments submitted by Applicants are deemed sufficient to overcome some of the rejections previously applied, the claims as amended contain subject matter which is not enabled for the following reasons. Claims 4, 7-10, 22, 35-39 are directed to structural homologs of the polynucleotide of SEQ ID NO: 1 of any function encoding a naturally-occurring variant of a polypeptide having kinase activity. Claims 11-12 are directed to a host cell comprising said polynucleotides and a method of producing the polypeptides encoded by said polynucleotides. While the claim recites the function of the polypeptide from which the variant is derived, there is no recitation of the function of the variant encoded by the claimed polynucleotides. The scope of the claims is not commensurate with the enablement provided in regard to the large number of polynucleotides of unknown function encompassed by the claims. As previously indicated, the state of the art teaches the unpredictability of assigning function based on structural homology. Therefore, one

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of skill in the art would have to go through the burden of undue experimentation to identify the function of the polynucleotides encompassed by the claims and determine a use for such polynucleotides. As such, one cannot reasonably conclude that the specification enables the full scope of the claims.

15. It is noted that the proposed amendment of claim 4 submitted by Applicants on 6/10/2003 appears to overcome the instant rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claim 4, 7-12, 22, 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Berlanga et al. (Eur. J. Biochem. 265:754-762, 1999; EMBL accession numbers AJ243533 and AJ243428; cited in the IDS).

This rejection has been discussed at length in Paper No. 18, mailed on 7/12/2002 and is now applied to claims 4, 7-12, 22, 31 for the following reasons. Claims 4, 7-8 and 22 are directed to a polynucleotide encoding a polypeptide of any function wherein said polynucleotide hybridizes under highly stringent conditions as recited in the claims. The human homolog (AJ243428) of Berlanga et al. comprises a fragment of 2161 bases encoding a polypeptide of 548 amino acid residues with 100% sequence identity to the polypeptide of SEQ ID NO: 2.

Therefore, the polynucleotide of Berlanga et al. would hybridize under the highly stringent

conditions recited in the claims to the polynucleotide of SEQ ID NO: 1. Claims 9-12, 31 are directed to vectors, host cells and a method of producing the polypeptide encoded by the polynucleotide of claim 4. Since Berlanga et al. also teaches the complete complement of the polynucleotide, host cells, vectors, and a method of producing the protein encoded by the polynucleotide (see Paper No. 18), the teachings of Berlanga et al. also anticipate claims 9-12 and 31 as written.

17. It is noted that the proposed amendment of claim 4 submitted by Applicants on 6/10/2003 and the cancellation of claim 35 may overcome the instant rejection.

18. Claim 4, 7, and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Duesterhoeft et al. (EMBL accession number AL137627 and AL157497; cited in the IDS).

This rejection has been discussed at length in Paper No. 18, mailed on 7/12/2002 and is now applied to claims 4, 7-8 and 22 for the following reasons. Claims 4, 7-8 and 22 are directed to a polynucleotide encoding a polypeptide of any function wherein said polynucleotide hybridizes under highly stringent conditions as recited in the claims. Duesterhoeft et al. teaches a nucleic acid molecule (AL157497) with 60.3% sequence homology to the polynucleotide of SEQ ID NO: 1 and comprises a fragment of 3332 nucleotides with 100% sequence homology to the polynucleotide of SEQ ID NO: 1. As such, the polynucleotide of Duesterhoeft et al. would hybridize under the highly stringent conditions recited in the claims to the polynucleotide of SEQ ID NO: 1. Therefore, the polynucleotide of Duesterhoeft et al. anticipate the claims as written.

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19. It is noted that the proposed amendment of claim 4 submitted by Applicants on 6/10/2003 and the cancellation of claim 35 may overcome the instant rejection.

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claims 1-4, 7-8, 32-33, 35-39 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/607,200, 09/644,867, 09/644,868, 09/644, 869, 09/644,871, 09/649,161, 09/652,109, 09/710,280, 09/716,475, 09/726,175, 09/726,176, 09/726,789 which have a common assignee (Millennium Pharmaceuticals Inc.) with the instant application. Based upon the earlier effective U.S. filing date of the copending applications, they would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. The instant copending applications all disclose the polynucleotide of SEQ ID NO: 1. It is noted that the effective filing date used is that of the provisional applications to which the copending applications claim priority to. The Examiner has not made any determination as to whether all the provisionals in the copending applications disclose the polynucleotide of SEQ ID NO: 1 in view of the fact that it is virtually impossible to determine whether the polynucleotide of SEQ ID NO: 1 was disclosed in the

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provisionals since the number of sequences disclosed is in the thousands and no computer readable forms were filed for these provisionals.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Conclusion

22. No claim is in condition for allowance.
23. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.
24. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 23, 2003


REBECCA E. P. DUTY
PRIMARY EXAMINER
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